Opening Statement
Chairman Fred Upton
Subcommittee on Health
Hearing on "FDA User Fees 2012: How Innovation Helps Patients and Jobs"
Wednesday, April 18, 2012

(As Prepared for Delivery)

I'd like to thank Chairman Pitts for holding today's hearing on the reauthorization of the Food and Drug Administration user fees and the impact of innovation on American patients and jobs.

Since the beginning of February, this subcommittee has held six hearings on the FDA. During these hearings, we've heard from witnesses from around the country on how Congress can help FDA become more predictable, consistent and transparent and how that will foster innovation here in the United States. I have heard this back home from my constituents too.

I think we all agree that fostering innovation helps American patients and aids in creating American jobs. As part of our efforts to foster innovation, we need to fix the recent problems with the investigational device exemption approval process and the medical device modifications guidance document. Recent FDA policy changes have created major problems, and we intend to use the user fee legislative process to rectify them.

I'd like to thank Ranking Member Waxman, Ranking Member Pallone, Mr. Dingell and the other Democratic members of the Energy and Commerce Committee for their bipartisan work on reauthorizing the user fees. During the past few months, we've had productive conversations on ways to improve the regulatory process at FDA.

As I said at the start of this process, we need to reauthorize the user fees by the end of June to assure continuity at the FDA and increase predictability for America's medical innovators and job creators. We still have work to do but because of the bipartisan commitment from members on both sides of the aisle, we are on track to do that.